Amendments to the Claims/Listing of Claims

Please amend claims 102 and 103 as follows. Please also cancel claim 106 without prejudice. This listing of claims will replace all prior versions, and listings, of claims in the application:

1-28. (Canceled).

29. (Withdrawn) A method for the administration of a taxane to a subject in need thereof, said method comprising systemically administering said taxane to said subject in a formulation that may be safely administered using medical hardware made from materials containing extractable components.

30. (Withdrawn) A method according to claim 29, wherein said medical hardware is selected from the group consisting of tubing, catheters, infusion bags, bottles, and syringes.

31. (Withdrawn) A method for the administration of a taxane to a subject in need thereof, said method comprising systemically administering said taxane to said subject in a formulation that may be safely administered without the use of an in-line filter.

32. (Withdrawn) A method for the administration of a taxane to a human subject in need thereof, said method comprising systemically administering a complete dose of said taxane to said subject in a volume of less than 250 ml.

33. (Withdrawn) A method according to claim 32, wherein said volume is less than 150 ml.

34. (Withdrawn) A method according to claim 32, wherein said volume is less than 60 ml.

35. (Withdrawn) A method for the administration of a taxane to a human subject in need thereof, said method comprising systemically administering said taxane to said subject at a rate between 6-30 mg/m^2/min over an administration period of one hour or less.

36-45. (Canceled).

46. (Withdrawn) A dry powder formulation suitable for administration of a taxane to a human subject in need thereof upon reconstitution, wherein said formulation comprises taxane nanoparticles having a mean particle size in the range of about 10 nm up to about 8 μm, wherein said formulation is substantially free of surfactant.

47. (Withdrawn) A formulation according to claim 46 wherein said formulation is lyophilized.

48. (Withdrawn) A frozen formulation of a taxane suitable for administration of a taxane to a subject in need thereof upon thawing.

49. (Withdrawn) A liquid formulation of a taxane suitable for administration to a human subject, said formulation comprising water and a taxane at a concentration of at least 2.0 mg/ml, wherein said formulation is stable for at least 3 days.

50. (Withdrawn) A liquid formulation of a taxane according to claim 49, wherein said taxane concentration is at least 5.0 mg/ml.

51. (Withdrawn) A liquid formulation of a taxane according to claim 49, wherein said taxane concentration is at least 10.0 mg/ml.

52. (Withdrawn) A drug formulation suitable for administration of drug to a subject in need thereof by inhalation or oral administration, said formulation comprising at least one protein and drug nanoparticles having a size of about 10-1,000 nm, plus optionally an excipient.

53. (Withdrawn) A method of making nanoparticles containing an active agent, said method comprising:

a) combining a non-volatile phase, a volatile phase, and a surfactant that spontaneously form a microemulsion, wherein said volatile phase contains said active agent; and

b) removing said volatile phase and thereby obtaining a suspension of solid nanoparticles in said non-volatile phase, wherein said nanoparticles contain said active agent and have an average diameter of less than 100 nm.

54. (Withdrawn) A method according to claim 53, wherein said nanoparticles have an average diameter of less than 50 nm.

55. (Withdrawn) A method according to claim 53, wherein said microemulsion further comprises a cosurfactant.

56. (Withdrawn) A method according to claim 53, further comprising:

c) removing said surfactant and/or cosurfactant by dialysis, ultrafiltration, or adsorption.

57. (Withdrawn) A method according to claim 53, further comprising:

c) removing essentially all of the remaining non-volatile phase by freeze-drying, spray-drying, or lyophilization, so as to obtain a dry powder of nanoparticles.

58. (Withdrawn) A method according to claim 57, further comprising:

d) resuspending said dry powder of nanoparticles in a pharmaceutically acceptable carrier.

59. (Withdrawn) A method according to claim 58, further comprising:

e) administering said resuspended nanoparticles to a patient.

60. (Withdrawn) A method according to claim 53, further comprising:

c) filtering said suspension of solid nanoparticles through a filter of sufficiently small pore size so as to sterilize said suspension.

61. (Withdrawn) A method of making nanoparticles containing an active agent, said method comprising:

a) combining a non-volatile phase and a volatile phase that spontaneously form a microemulsion, wherein said non-volatile phase contains said active agent; and

b) removing said non-volatile phase and thereby obtaining solid nanoparticles in said volatile phase, wherein said nanoparticles contain said active agent and have an average diameter of less than 100 nm.

62. (Withdrawn) A suspension of nanoparticles made by the method of claim 53.

63. (Withdrawn) Dry nanoparticles made by the method of claim 57.

64. (Withdrawn) A suspension of nanoparticles made by the method of claim 58.

65. (Withdrawn) A suspension of nanoparticles made by the method of claim 61.

66. (Withdrawn) A dry powder formulation of a taxane suitable for administration of a taxane to a subject in need thereof upon reconstitution, wherein said formulation is substantially free of surfactants.

67. (Withdrawn) A dry powder formulation of a taxane suitable for administration of a taxane to a subject in need thereof upon reconstitution, wherein said formulation is substantially free of cremophor.

68-69. (Canceled).

70. (Withdrawn) A lyophilized formulation suitable for administration of a taxane to a subject upon reconstitution, wherein said formulation comprises taxane nanoparticles whose size remains substantially constant prior to and after reconstitution.

71. (Withdrawn) An article of manufacture comprising a sealed vial containing a dry powder formulation of a taxane, wherein said formulation comprises taxane nanoparticles having an average diameter in the range of about 10 nm up to about 8 μm.

72. (Withdrawn) An article of manufacture according to claim 71, wherein said formulation is stable for at least 3 days.

73. (Previously presented) An article of manufacture comprising a dry powder or liquid formulation of drug and at least one protein, wherein said formulation comprises drug nanoparticles that have been filtered through a sterilizing filter.

74. (Previously presented) An article of manufacture according to claim 73 wherein said drug is a taxane.

75. (Previously presented) An article of manufacture according to claim 74, wherein said liquid formulation of taxane is free of surfactants.

76. (Withdrawn) The method of claim 35 wherein said rate is between 6-16 $mg/m^2/min$.

77. (Withdrawn) The method of claim 35 wherein said taxane is used to treat cancer in said human subject.

78. (Withdrawn) The method of claim 35 wherein said taxane is used to treat vascular restenosis in said human subject.

79. (Withdrawn) The formulation of claim 46 wherein said nanoparticles have a mean particle size in the range of about 29 nm up to about 400 nm.

80. (Withdrawn) The formulation of claim 46 wherein said dry powder formulation of taxane is suitable for the treatment of tumors in the brain or peritoneal cavity.

81. (Withdrawn) A liquid formulation of a taxane according to claim 49, wherein said taxane concentration is at least 20 mg/ml.

82. (Withdrawn) A method for the administration of a taxane to a human subject in need thereof, said method comprising systemically administering said taxane to said subject at a concentration of at least 2 mg/ml.

83. (Withdrawn) The method of claim 82 wherein said concentration of said taxane is at least 5 mg/ml.

84. (Withdrawn) The method of claim 82 wherein said concentration of said taxane is at least 10 mg/ml.

85. (Withdrawn) The method of claim 82 wherein said concentration of said taxane is at least 20 mg/ml.

86. (Withdrawn) The formulation of claim 52 wherein said drug nanoparticles are contained within protein microparticles having a size of about 10 nm to about 8 μm.

87. (Withdrawn) The formulation of claim 52 wherein said drug formulation may be used in conjunction with oral bioavailability enhancers.

88. (Withdrawn) An article of manufacture comprising a drug formulation in a sealed vial suitable for administration of a drug to a human subject in need thereof, said formulation comprising at least one protein and drug nanoparticles having a size in the range of about 10 nm up to about 1000 nm.

89. (Withdrawn) The article of claim 88 wherein said drug formulation is a dry powder.

90. (Withdrawn) The article of claim 88 wherein the drug formulation is a liquid.

91. (Withdrawn) The article of claim 88 wherein said drug is hydrophobic.

92. (Withdrawn) A formulation of paclitaxel suitable for administration to a human subject in need thereof wherein the pharmacokinetics are such that the area under the curve (AUC) for paclitaxel in said formulation is significantly less than the AUC for paclitaxel in TAXOL at the same dose.

93. (Withdrawn) A formulation of paclitaxel suitable for administration to a human subject in need thereof wherein the pharmacokinetics are such that half-life for paclitaxel in said formulation is significantly higher than the half-life for paclitaxel in TAXOL at the same dose.

94. (Withdrawn) A formulation according to claim 49 wherein said formulation further comprises one or more of albumin, a polyalkylene glycol, or an oil.

95. (Withdrawn) A formulation according to claim 94 wherein said oil is an oil-soluble vitamin.

96. (Withdrawn) A formulation according to claim 95 wherein said vitamin is vitamin A, vitamin D, vitamin E or vitamin K.

97. (Withdrawn) A formulation according to claim 49 wherein said taxane is non-crystalline.

98. (Withdrawn) A formulation according to claim 52 wherein said protein is albumin.

99. (Withdrawn) A formulation according to claim 52 wherein said formulation is solid or liquid.

100. (Withdrawn) A method according to claim 61 wherein said active agent is selected from the group consisting of an anti-neoplastic, an anesthetic and a hormone.

101. (Previously presented) An article of manufacture according to claim 73 wherein said protein is albumin.

102. (Currently amended) An article of manufacture according to claim 73 wherein said ~~formulation~~ nanoparticle is solid or liquid.

103. (Currently amended) An article of manufacture according to claim 73 wherein said drug is selected from the group consisting of an anti-neoplastic, and an anesthetic ~~and a hormone~~.

104. (Previously presented) An article of manufacture according to claim 103 wherein said anti-neoplastic is a taxane.

105. (Previously presented) An article of manufacture according to claim 103 wherein said anesthetic is propofol.

106. (Canceled).

107. (Previously presented) A formulation according to claim 73 wherein said drug is non-crystalline.

108. (Previously presented) A formulation according to claim 73 wherein said nanoparticles are suitable for administration to a subject by oral, topical, ocular, intramuscular, intravenous, intraperitoneal, intraarterial, intraurethral, intrathecal, or inhalation administration.

109. (Withdrawn) An article of manufacture according to claim 88 wherein said formulation is solid or liquid.

110. (Withdrawn) An article of manufacture according to claim 88 wherein said drug is selected from the group consisting of an anti-neoplastic, an anesthetic and a hormone.

111. (Withdrawn) An article of manufacture according to claim 110 wherein said anti-neoplastic is a taxane.

112. (Withdrawn) An article of manufacture according to claim 110 wherein said anesthetic is propofol.

113. (Withdrawn) An article of manufacture according to claim 110 wherein said hormone is a thyroid hormone.

114. (Withdrawn) An article of manufacture according to claim 88 wherein said drug is non-crystalline.

115. (Withdrawn) A formulation according to claim 92 further comprising one or more of albumin, a polyalkylene glycol, and an oil.

116. (Withdrawn) A formulation according to claim 115 wherein said oil is an oil-soluble vitamin.

117. (Withdrawn) A formulation according to claim 115 wherein said vitamin is vitamin A, vitamin D, vitamin E or vitamin K.

118. (Withdrawn) A formulation according to claim 92 wherein said paclitaxel is non-crystalline.

119. (Withdrawn) A formulation according to claim 93 further comprising one or more of albumin, a polyalkylene glycol, and an oil.

120. (Withdrawn) A formulation according to claim 119 wherein said oil is an oil-soluble vitamin.

121. (Withdrawn) A formulation according to claim 119 wherein said vitamin is vitamin A, vitamin D, vitamin E or vitamin K.